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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,112	10/28/2003	Frank B. Gelder	VIR-021011CO01	4731

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
10/695,112	10/28/2003	Gelder, F. B.	VIR-021011CO01

EXAMINER	
Jeffrey S. Parkin, Ph.D.	
ART UNIT	PAPER NUMBER
1648	03/04/2006

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application
Commissioner of Patents

This application contains sequence disclosures (e.g., see pages 3-25 and 28) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §s 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §s 1.821-1.825. Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the

Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

04 March, 2006

Notice to Comply	Application No. 10/695,112	Applicant(s) Gelder, F. B.	
	Examiner Jeffrey S. Parkin	Art Unit 1648	10/28/2003

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial ~~or substitute~~ computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial ~~or substitute~~ paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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p17 is exposed on the surface of infected lymphocytes following budding. This provides an additional target for ADCC lysis of infected lymphocytes.

One of the specific peptides set forth above, comprising at least one epitope not recognized by antibodies from HIV-infected patients but recognized by goat anti-HIV antibodies, is the peptide comprising amino acid residues 4 through 27 of $HIV1_{SF2}$ envelope gp120 protein and linear epitope-containing subsequences thereof, which has the following sequence:

K G T R R N Y Q H L W R W G T L L L G M L M I C

This peptide mimics human proteins FOL1, NTCR, PIP5, PSS1, KLTK, MC5R, ECP, INIU, INI9, VPRT, CD69, M[illegible]E, RNKD, ACHE, TCO2, LCAT, MAG1, MAG2, MAG3 and LYOX.

A second epitope region from the HIV1SF2 gp120 envelope glycoprotein extends from amino acid residue 54 through 76, which has the sequence:

A S D A R A Y D T E V H N V W A T H A C V P T

This peptide mimics proteins CYRB and SYV.

A third epitope region of interest in the envelope of $HIV1_{SF2}$ extends from amino acid residue numbers 502 through 541 of glycoprotein gp41. This peptide has the following amino acid sequence:

HIV1_Env502

R V V Q R E K R A V G I V G A M
F L G F L G A A G S T M G A V S
L T L T V Q A R 502-541

This peptide mimics human proteins CYPC, TYK2, ACHE, NTCF, NTCR, CD81, 41BL, NIDO, GSHR, CO02 and TCO2.

In another specific embodiment, an epitope region of interest is that of amino acid residues 2 through 23 of the $HIV1_{SF2}$ Gag protein p17. This peptide has the sequence:

G A R A S V L S G G E L D R W E K I R L R P

This peptide mimics human proteins TFPI, PA2M, BLSA, ECP, and FETA and certain neurotoxins, such as NXS1 and NAJAT. The peptide has a hydrophobic sequence which binds to and targets host cell membrane and function mimics cellular translation protein Src.

A second target on $HIV1_{SF2}$ p17 extends from amino acid residue 89 through 122. This peptide has the sequence:

L Y C V H Q R I D V K D T K E A L E K I E E E Q N K S K.

This peptide mimics FETA and TRIC.

Another peptide of interest is that of amino acid residues 166 through 181 of the Gag gene protein p24 and epitope containing subsequences therein. This peptide has the sequence:

P E V I P M F S A L S E G A T P

This peptide mimics human proteins FETA and TRFL.

A third Gag gene protein epitope region of interest is the peptide having amino acid residues 390 through 410 and 438-443 of Gag gene protein p7 and epitope containing subsequences thereof. This peptide has the sequence:

K T V K C F N C G K E G H I A K N C R A P + K I W S S Q

This peptide mimics human FETA and RNA binding proteins. This peptide contains a zinc binding domain which interacts with, and binds to, viral RNA. Antibodies to this region enhance the removal of premature HIV devoid of envelope following the lysis of infected CD4+ lymphocytes.

Also of interest as an epitope region is the peptide of amino acid residues 69 through 94 of the

protease p10 and epitope-containing subsequences thereof. This peptide has the sequence:

R I G G Q L K E A L L D T G A D D T V L E E M N L P

This peptide sequence mimics human proteins RENI, BLSA, VPRT and CATD. Antibodies to this sequence inhibit the protease activity of HIV.

A further specific sequence useful in this invention is a sequence encompassing amino acid residues 254 through 295 of HIV1 reverse transcriptase heterodimer p66/55. This peptide has the sequence:

G L K K K K S V T V L D V G D A Y F S V P L D K D
F R K Y T A F T I P S I N N E T P

This peptide sequence mimics human proteins POL1 and ECP.

As noted above, other strains of HIV also can be used to obtain peptides and antibodies in accordance with the present invention. Useful peptides from other strains can be determined by comparing and aligning the sequence of another strain to the sequence of $HIV1_{SF2}$ or $HIV2_{NZ}$ and finding that part of the sequence homologous to the epitopes of interest identified for $HIV1_{SF2}$ or $HIV2_{NZ}$.

A sequence of interest in $HIV2_{NZ}$ identified by the method of this invention is in the env gp120 open reading frame and extends from amino acid residue numbers 7 through 43. This peptide has the following sequence:

Q L L I A I V L A S A Y L I H C K Q F
V T V F Y G I P A W R N A S I P L F

This peptide mimics human proteins IL9, SRE1, NRM1, LBP, NOL1, S5A2, LMA1, LECH, LFA3, KPLC, FETA, 3BH2, 3BH1, INR2 and EV2B.

As an example, useful truncated sequences of the peptide extending from amino acid residue 502 through 541 of $HIV1_{SF2}$ gp41 discussed above include a peptide with the sequence of amino acid residues 512-531:

G I V G A M F L G F L
G A A G S T M G A

and also a sequence extending from amino acid residue 518 through amino acid residue 527:

F L G F L G A A G S

Another particularly useful truncated peptide is a truncated sequence of the peptide extending from anino acid 7 through 43 of gp120 of $HIV2_{NZ}$ has the following sequence

L L T A I V L A S A Y L I H C K Q

The peptide can be prepared in a wide variety of ways. The peptide, because of its relatively small size, can be synthesized in solution or on a solid support in accordance with conventional techniques. Various automatic synthesizers are commercially available today and can be used in accordance with known protocols. See, for example, Stewart and Young, *Solid Phase Peptide Synthesis*, 2nd ed., Pierce Chemical Co., 1984; and Tam et al., *J. Am Chem. Soc.* (1983) 105:6442.

Alternatively, hybrid DNA technology can be employed where a synthetic gene is prepared by employing single strands which code for the polypeptide or substantially complementary strands thereof, where the single strands overlap and can be brought together in an annealing medium so as to hybridize. The hybridized strands then can be ligated to form the complete gene, and, by choice of appropriate termini,